

Applicant : Jens Ponikau  
Serial No. : 09/177,273  
Filed : October 22, 1998  
Page : 2

Attorney's Docket No.: 07039-129001

RECEIVED

Please add claims 51-104 as follows:

SEP 25 2000

~~18~~  
~~51.~~ The method of claim 1, wherein said antifungal agent comprises an antifungal agent selected from the group consisting of ketoconazole, itraconazole, saperconazole, and voriconazole.

~~19~~  
~~52.~~ The method of claim 1, wherein said antifungal agent comprises amphotericin B.

~~20~~  
~~53.~~ The method of claim 1, wherein said antifungal agent comprises itraconazole.

~~21~~  
~~54.~~ The method of claim 1, wherein said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent.

~~22~~  
~~55.~~ The method of claim 1, wherein said formulation comprises about 1 ng to about 500 mg of said antifungal agent.

~~23~~  
~~56.~~ The method of claim 1, wherein said formulation comprises about 100 mg of said antifungal agent.

~~24~~  
~~57.~~ The method of claim 1, wherein said formulation comprises a plurality of antifungal agents.

~~25~~  
~~58.~~ The method of claim 1, wherein said effective amount of said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent per kg of body weight of said mammal.

~~26~~  
~~59.~~ The method of claim 1, wherein said effective amount of said formulation comprises about 1 ng to about 500 mg of said antifungal agent per kg of body weight of said mammal.

~~27~~  
~~60.~~ The method of claim 1, wherein said effective amount of said formulation remains constant during said effective duration.

Applicant : Jens Ponikau  
Serial No. : 09/177,273  
Filed : October 22, 1998  
Page : 3

Attorney's Docket No.: 07039-129001

RECEIVED

SEP 25 2000

TECH CENTER 1500/2900

28  
61.

The method of claim 1, wherein said effective frequency of said mucoadministration is from about four times a day to about once every other week.

29  
62.

The method of claim 1, wherein said effective frequency of said mucoadministration is from about twice a day to about once a week.

30  
63.

The method of claim 1, wherein said effective frequency of said mucoadministration is more frequent than once a day.

31  
64.

The method of claim 1, wherein said effective frequency of said mucoadministration is more frequent than once a week.

32  
65.

The method of claim 1, wherein said effective duration is greater than about 60 days.

33  
66.

The method of claim 1, wherein said effective duration is greater than about 90 days.

34  
67.

The method of claim 1, wherein said formulation comprises a compound selected from the group consisting of pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

35  
68.

The method of claim 1, wherein said method comprises administering to said mammal a second formulation.

36  
69.

The method of claim 35, wherein said second formulation comprises a compound selected from the group consisting of antifungal agents, pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

RECEIVED

SEP 25 2000

2/28/00

37

70. The method of claim 1, said method comprising, after said mucoadministration, prophylactically mucoadministering to said mammal a prophylactic formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said prophylactic formulation comprising an antifungal agent.

38

71. The method of claim 70, wherein said prophylactic mucoadministration comprises direct mucoadministration.

37

39

72. A method for prophylactically treating a mammal at risk for developing non-invasive fungus-induced intestinal mucositis, comprising mucoadministering to said mammal a formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

40

73. A method for treating a mammal having a non-invasive fungus-induced intestinal mucositis, comprising the steps of:

a) identifying said mammal, and

b) mucoadministering to at least a portion of the digestive tract of said mammal a formulation in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent, wherein said mucoadministration comprises orally applying said formulation to said digestive tract, and wherein said duration is greater than about 30 days.

41

74. A method for prophylactically treating a mammal at risk for developing non-invasive fungus-induced intestinal mucositis, comprising the steps of:

a) identifying said mammal, and

b) mucoadministering to at least a portion of the digestive tract of said mammal a formulation in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent.

Applicant : Jens Ponikau  
Serial No. : 09/177,273  
Filed : October 22, 1998  
Page : 5

Attorney's Docket No.: 07039-129001

42  
75. An article of manufacture, comprising packaging material and a formulation contained within said packaging material, wherein said formulation comprises an antifungal agent and wherein said packaging material comprises a label or package insert indicating that said formulation can be mucoadministered to a mammal having non-invasive fungus-induced intestinal mucositis in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis.

RECEIVED

SEP 25 2000

TECHNICAL STAFF

43  
76. An article of manufacture, comprising packaging material and a formulation contained within said packaging material, wherein said formulation comprises an antifungal agent and wherein said packaging material comprises a label or package insert indicating that said formulation can be mucoadministered to a mammal at risk for developing non-invasive fungus-induced intestinal mucositis in an amount, at a frequency, and for a duration effective to prevent said non-invasive fungus-induced intestinal mucositis.

B3 cont  
44  
77. A method for treating a human having non-invasive fungus-induced intestinal mucositis, comprising mucoadministering to the digestive tract of said human a formulation in an amount, at a frequency, and for a duration effective to reduce or eliminate said non-invasive fungus-induced intestinal mucositis, said formulation comprising an antifungal agent, wherein said mucoadministration comprises orally applying said formulation to said digestive tract, and wherein said frequency is from about twice a day to about once a week.

45  
78. The method of claim 77, wherein said human is immunocompetent.

46  
79. The method of claim 77, wherein said non-invasive fungus-induced intestinal mucositis is characterized by polyp formation or polypoid change.

47  
80. The method of claim 77, wherein said formulation is in the form of a capsule.

48  
81. The method of claim 80, wherein said capsule is a regulated release capsule.

~~49~~ 48  
~~82.~~ The method of claim ~~81~~, wherein said regulated release capsule is a pH regulated release capsule.

~~50~~ 48  
~~83.~~ The method of claim ~~81~~, wherein said regulated release capsule is a time regulated release capsule.

~~51~~ 44  
~~84.~~ The method of claim ~~77~~, wherein said mucoadministration is a direct mucoadministration.

~~52~~ 44  
~~85.~~ The method of claim ~~77~~, wherein said antifungal agent comprises an azole.

~~53~~ 44  
~~86.~~ The method of claim ~~77~~, wherein said antifungal agent comprises an antifungal agent selected from the group consisting of ketoconazole, itraconazole, saperconazole, voriconazole, flucytosine, miconazole, fluconazole, griseofulvin, clotrimazole, econazole, terconazole, butoconazole, oxiconazole, sulconazole, ciclopirox olamine, haloprogin, tolnaftate, naftifine, terbinafine hydrochloride, morpholines, nystatin, natamycin, butenafine, undecylenic acid, Whitefield's ointment, propionic acid, and caprylic acid.

~~54~~ 44  
~~87.~~ The method of claim ~~77~~, wherein said antifungal agent comprises an antifungal agent selected from the group consisting of ketoconazole, itraconazole, saperconazole, and voriconazole.

~~55~~ 44  
~~88.~~ The method of claim ~~77~~, wherein said antifungal agent comprises amphotericin B.

~~56~~ 44  
~~89.~~ The method of claim ~~77~~, wherein said antifungal agent comprises itraconazole.

~~57~~ 44  
~~90.~~ The method of claim ~~77~~, wherein said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent.

58 91. The method of claim 77, wherein said formulation comprises a plurality of antifungal agents.

59 92. The method of claim 77, wherein said effective amount of said formulation comprises about 0.01 ng to about 1000 mg of said antifungal agent per kg of body weight of said human.

60 93. The method of claim 77, wherein said effective amount of said formulation comprises about 1 ng to about 500 mg of said antifungal agent per kg of body weight of said human.

61 94. The method of claim 77, wherein said effective amount of said formulation remains constant during said effective duration.

62 95. The method of claim 77, wherein said effective duration is greater than about 7 days.

63 96. The method of claim 77, wherein said effective duration is greater than about 14 days.

64 97. The method of claim 77, wherein said effective duration is greater than about 30 days.

65 98. The method of claim 77, wherein said effective duration is greater than about 60 days.

66 99. The method of claim 77, wherein said effective duration is greater than about 90 days.

67 100. The method of claim 77, wherein said formulation comprises a compound selected from the group consisting of pharmaceutically acceptable aqueous vehicles, pharmaceutically acceptable solid vehicles, mucolytic agents, antibacterial agents, anti-inflammatory agents, immunosuppressants, dilators, vaso-constrictors, steroids, and therapeutic compounds.

68 101. The method of claim 77, wherein said method comprises administering to said human a second formulation.